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UNITED STATES DEPARTMENT OF COMMERCE
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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

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Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,164,194, was filed on December 18, 1996, under 35 U.S.C. § 156. U.S. Patent No. 5,164,194 issued on November 17, 1992 from an application that claimed priority to an application that was filed on November 9, 1988. Accordingly, the original expiration date of the patent is November 17, 2009.

The assistance of your Office is requested in confirming that the product identified in the application, Astelin, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.


Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Kevin B. Clarke, Esq.
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